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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/970,436
Filing Date	October 3, 2001
First Nam d Inventor	Kishor B. Par kh
Group Art Unit	1615
Examiner Name	Liliana Di Nola Baron
Attorney Docket Number	MCP-297
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Examiner Name	Liliana Di Nola Baron
Attorney Docket Number	MCP-297

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
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Kishor B. Parekh		
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		U.S. Patent Document  Kind Code <sup>2</sup>		Name of Patentee or Applicant	Date of Publication of Cited Document	Pages, Columns, Lines, where relevant passages
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W VIB		159,821		Thomson 2/16/8/5	7/26/1926	·
9 <del>0 MAZ</del> i		540,538		Collon	6/4/1895	
_		599,865		Richards	3/1/1898	
	<u> </u>	724,436		Clark	4/7/1903	
_		1,115,426		Green	10/27/1914	
$\dashv$		1,377,644		Warrington	5/10/1921	
+	<del>                                     </del>	1,872,190		Sindl	8/16/1932	
+-	1	2,344,000		Read	3/14/1944	
	<del>                                     </del>	2,370,698		Vaughn	3/6/1945	
+	$\dagger$	2,373,721		Taylor et al.	4/17/1945	
1	$\vdash$	2,790,548		Scherer	4/30/1957	
	+-	2,823,789		Henning	2/18/58	
	+-	2,847,809		Lindeman et al.	8/19/1958	
	1-	3,011,678		McClosky et al.	12/5/1961	
-+	+-	3.045.641		Oddo	7/24/1962	
+	-	3,141,792		Lactman et al.	7/21/1964	
-	+	3,148,775		Briel, Jr. et al.	9/15/1964	·
	+	3,150,765		Elfis	9/29/1964	
	+	3,181,689		Van Der Winden	5/4/1965	
	+-	3,185,626		Baker	5/1965	
	+	3,228,789		Glassman	1/11/1966	
	+	3,339,799		Spisak	9/5/1987	
	+-	3,453,989		Bippus	7/8/1969	
	+-	3,538,997		Chistine	11/10/70	·
	+-	3,543,908		Holland	12/1/70	
<del></del>	+	3,552,536		Emary	1/5/1971	
	+-	3,573,966		Hostetler	4/6/1971	
$\dashv$	+	3,692,562		Kawata et al.	9/19/1972	
$\dashv$	+-	3,838,791		Raitt	10/1/1974	
	1	3,884.143		Ackely	5/20/1975	8
	+	3,898,762		Banker	7/29/1975	CEN
-	+-	3,997,058		Grear et al.	12/14/1976	H 2 2 1
1	+	4 177 254		Khan et al.	12/4/1979	4 2 R 16
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09/970,436 U.S. Patent Document Pages, Columns, Lines, where relevant passages **Date of Publication** Name of Patentee or Applicant of Cited Document Kind Code Cite Examiner of Cited Document or relevant figures appear Initials (if known) mm-dd-yyyy Number No.1 2/26/1980 Sono Ackely, Sr. et al. 4.189,996 5/27/1980 Moser et al. 4,204,951 9/16/1980 Kurek et al. 4,222,168 10/21/1980 Watzka et al. 4/228,901 Cherukuri et al. 12/9/1980 4,238,510 4/9/1985 Sakashita et al. 4,510,168 6/11/1985 Garbis et al. 4,522,149 7/2/1985 Braden 4,526,129 12/31/1985 4,562,024 Rogerson\* 4/2919/88 Bailey 4,585,764 5/20/1986 4,590,183 Bailey 3/24/1987 Mabboux et al. 4,651,880 6/2/1987 Delgado et al. 4,669,416 8/4/1987 4,684,113 Douglas et al. 12/29/1987 Blank et al. 4,716,042 4/5/1988 Focke 4,735,032 1/1019/89 Pich et al. 4,797,287 3/28/1989 Matthews et al. 4,818,259 4/11/1989 Radebaugh et al. 4,820,522 4/11/1989 Berta 4,820,524 5/9/1989 Pich et al. 4.828.843 7/25/1989 Tencza et al. 4,851,230 9/19/1989 Berta 4,867,983 11/14/1989 4,880,101 Wiggins 5/1/1990 Berta 4,921,108 10/23/1990 4,965,089 Sauter et al. 2/5/1991 Berta 4,990,358 10/30/1990 Berta 4,966,771 7/16/1991 5,032,074 Muto et al. 10/8/1991 Tait et al. 5,054,258 9/18/1992 Sadek et al. 5,146,730 Tordini 10/20/1992 5,155,981 7/20/1993 Berta 5,228,918 8/10/1993 5,234,099 Berta

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Pastecki et al.

5,314,537

5,391,230

5,436,026

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7/25/1996

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TRADE	A		U.S. Patent Doo	zument		Date of Publication	Pages, Columns, Lines,
THE	Examiner Initials	Cite No.'	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	of Cited Document mm-dd-yyyy	where relevant passages or relevant figures appear
	TICK	1	5,514,216	•	Pastecki et al.	5/7/1996	
		1	5,607,044		Berta	3/4/1997	
			5,651,191		Watunas et al.	7/29/1997	
·	-1/	,b	5,658,589		Parekh et al.	8/19/1997	
	11	ৰা	5,916,592		Parekh et al.	6/29/1999	

FOREIGN PATENT DOCUMENTS Pages, Columns, Lines, Date of Publication Foreign Patent Document of Cited Document where relevant Name of Patentee or passages or relevant T<sup>6</sup> mm-dd-yyyy Cite Examiner Applicant of Cited Document figures appear KindCode<sup>5</sup> Initials Number<sup>4</sup> Office<sup>3</sup> No.' mm- 5-1985 Shinetsu Chem Ind KK (abstract) JP 60084215 9-1961 N/A 69027916 Sankyo Co .Ltd. (abstract) JP Premisi Inc. Liu. (abstract) 7311641Z Dailchi-Selyaku Co. Ltd. (abstract) N/A 6645552 JP عر 65009994 Konishi (abstract) N/A Konishi (abstract) JΡ £5009999 8/104L 3/1 JP 41-13997 13/06/1984 Eisai Co., Ltd **B1** EΡ 0 023 327 19/09/1984 Takeda Chemical Industries EΡ 0 118 856 A1 13/06/1985 BASE 0 166 315 АЗ EΡ 09/17/1986 Rt Merck EP 0 194 502 25/11/1987 Fukushima 0.246.693 81 FP EPY 8/1988 0 279 282 EP SPY 8/1989 0 319 318 EΡ Cax 1/1987 1217140 CA 6/1987 CA 1223209 10/1987 2588188 FR 2/1975 24 34 803 ĐΕ 1/1986 **A3** 0 166 315 DE 6/1827 445 365 DE 3/1969 NZ 142947 V, S.X 1/1986 NZX 214983 NZ 10/1928 127081 CH

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281183		and 438  Porter, Stuart C., "Coating of Pharmaceutical Dosage Forms", Remington's Pharmaceutical Sciences, Capt. 91, pp. 1633- 1643 17th Edition, Mack Publ. Co. (1985)	•
		Product info.: Vector/Freund "hi-coaters"	
		Product lofe: Glett Coater	
		Product Info.: Cherry Burrell Gelatin Capsule Machine  Van Hostetler and J. Q. Bellard, Chapter 13 "Capsules", The Theory and Practice of Industrial Pharmacy, pp. 389-398.	
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